IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

MEDTRONIC INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civ. No. 03-848-SLR
	)	
GUIDANT CORPORATION, GUIDANT SALES CORPORATION, ELI LILLY & COMPANY, MIROWSKI FAMILY VENTURES L.L.C.,	)	
	)	
Defendants.	)	

Karen Jacobs Louden, Esq. and Philip Bangle, Esq. of Morris, Nichols, Arsht & Tunnell, Wilmington, Delaware. Counsel for Plaintiff. Of Counsel: Steven C. Schroer, Esq. of Fitch, Even, Tabin & Flannery, Boulder, Colorado, Timothy E. Levstik, Esq. and Mark A. Borsos, Esq. of Fitch, Even, Tabin & Flannery, Chicago, Illinois.

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OPINION

Dated: July 19, 2005
Wilmington, Delaware

ROBINSON, Chief Judge

I. INTRODUCTION

On August 29, 2003, plaintiff Medtronic, Incorporated filed this declaratory judgment action against defendants Guidant Corporation, Guidant Sales Corporation, Eli Lilly and Company and Mirowski Family Ventures. (D.I. 1) Plaintiff's complaint alleges that claims 15-26 of U.S. Patent No. RE38,119 ("the RE'119 patent") are invalid.[1] (Id.) On September 12, 2003, plaintiff filed an amended complaint, which was answered by defendants on September 23, 2003. (D.I. 4, 11) Defendants amended their answer on September 25, 2003. (D.I. 12)

The parties have agreed that the issues in this case are limited and involve only the validity of the RE'119 patent and whether the RE'119 patent improperly recaptures subject matter. (PX 69.5) The court has jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202. A three day bench trial commenced on November 1, 2004. The following are the court's findings of fact and conclusions of law pursuant to Fed. R. Civ. P. 52(a).[2]

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[1]The RE'119 patent is the reissue of U.S. Patent No. 4,928,688 ("the '688 patent").

[2]Prior to the bench trial, the court granted Medtronic's motion in limine no. 2, precluding defendants from relying on attorney error, pending an in camera review of the documents listed on defendants' privilege log. (D.I. 105) After reviewing the documents, the court found that defendants were using the attorney-client privilege as both a sword and shield and, as such, had waived the privilege as to all relevant documents. (D.I. 115) As directed, defendants produced the documents, but

II. FINDINGS OF FACT

A. The Parties

1. Plaintiff is a medical device manufacturer and competitor of Guidant. (D.I. 4 at ¶¶ 1, 3, D.I. 12 at ¶ 3) Defendant Mirowski Family Ventures is the assignee of the RE'119 patent. (PX 2) Defendant Eli Lilly is the exclusive licensee of the RE'119 patent with an obligation to enforce the patent. (D.I. 4 at ¶ 2; D.I. 12 at ¶ 2) Defendant Guidant is a medical device manufacturer that was formed in 1994 when Eli Lilly divested certain assets. (D.I. 4 at ¶ 3) Defendant GSC is a wholly owned subsidiary of defendant Guidant. (D.I. 4 at ¶ 4, D.I. 12 at ¶ 4)

2. In 1991, plaintiff, defendant Eli Lilly and defendant Guidant's wholly-owned subsidiary, Cardiac Pacemakers, Inc. ("CPI"), entered into a Settlement and License Agreement ("the Agreement") to settle several lawsuits with respect to numerous patents relating to implantable pacemakers and defibrillators. (PX 69.1) Under the Agreement, any infringement of a covered

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not all of them were admitted at trial. ACS now requests that Medtronic return or destroy the documents that it did not rely on at trial.

The court's order was an effort to strike a fair balance at trial and prevent defendants from making arguments in its defense that relied on documents never produced to Medtronic. The court did not intend to give Medtronic access to documents that were not relevant to its claims. Therefore, defendants' motion for the return or destruction of those documents produced, but not used at trial, is granted.

patent by a party, without the payment of royalties, can be the subject of litigation.[3] (Id.)

B. Dr. Mower's Invention

3. Dr. Morton Mower, at a time when he was employed by CPI, invented a device to treat ventricular asynchrony, a condition in which the patient has a conduction defect in his ventricles causing the ventricles to contract at different times. (D.I. 122 at 89; PX 77; PX 80)

4. The heart is made up of four chambers, two atria and two ventricles. (D.I. 122 at 78-80) Electrical stimulations, also known as depolarizations, within these chambers cause contractions within the heart which result in pumping. (Id.) This electrical activity arises in the sinoatrial node ("the SA node") in the right atrium. (Id.) It passes through the atrium to the atrial ventricular node ("the A-V node") and is then transmitted to the ventricles. (Id.) The period of time from depolarization of the atria to depolarization of the ventricles is called the "A-V delay period" and it usually lasts about 150 milliseconds. (D.I. 122 at 82-83)

5. Dr. Mower's device either conditionally or unconditionally paces the ventricles of the heart, so as to cause

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[3]Under this provision, defendants notified Medtronic that they believed some of Medtronic's devices infringed certain claims of the RE'119 patent. (PX 69.5) Medtronic responded to the allegations by filing this declaratory judgment action.

simultaneous ventricular contractions. The conditional embodiment, which was explicitly claimed in the '688 patent, requires sensing a depolarization in a first ventricle, then waiting for a predetermined period of time to sense a depolarization in the second ventricle. (D.I. 122 at 92; D.I. 123 at 331) If no depolarization is sensed in the second ventricle, then the device electronically paces the second ventricle (i.e., paces the second ventricle). (D.I. 123 at 331) The unconditional embodiment requires sensing depolarization in either ventricle and, as soon as depolarization in one ventricle is sensed, both ventricles are immediately paced. (Id. at 332; D.I. 122 at 105) In the unconditional embodiment, one ventricle will necessarily be paced twice, once naturally and once by the device. However, this does not damage the ventricle because each ventricle has a refractory period. (D.I. 123 at 332)

C. Prosecution Of The '688 Patent

6. In the late 1980's, Dr. Mower contacted Mr. Ron Cohn to draft a patent application for his invention. (D.I. 123 at 245) Mr. Cohn was the attorney who primarily prosecuted patents for the Mirowski Family Ventures. (D.I. 122 at 186)

7. On October 30, 1987, Stuart Rickerson, an agent of CPI, forwarded Mr. Cohn's draft to Thomas Nikolai and requested that Mr. Nikolai review and prepare a final draft application. (PX 74) On December 3, 1987, Mr. Nikolai notified Dr. Mower that CPI

had requested that he "assist" Mr. Cohn in preparing the patent application. (PX 75) Attached to this letter was a copy of the application, as drafted by Mr. Cohn and revised by Mr. Nikolai. (PX 75) Mr. Nikolai asked Dr. Mower to review the draft and send any corrections back to him. (PX 75) Mr. Nikolai further inquired about whether the specification accurately described the invention. (PX 75) Specifically, Mr. Nikolai stated that,

> [i]n reading through the patent specification, especially the portion relating to the logic diagram of Figure 2, you will note that we have included the concept of a "window of coincidence" which we think is important. It seems to be logically impossible to make a decision about pacing or not pacing unless such a "window of coincidence," however small, is provided in which the circuitry can look for a pulse from the other ventricle. I am further operating on the assumption that the degree of coincidence of the two pulses might very well be a variable which one would want to program in the same way that rate, pulse width, AV delay, etc., are programmed in many present-day pacers.

(PX 75)

8. During the summer of 1988, Dr. Mower and Mr. Cohn discussed the draft application sent to Dr. Mower by Mr. Nikolai. (D.I. 123 at 276; PX 76) Mr. Cohn forwarded Dr. Mower's comments to Mr. Nikolai, instructing him to "use these comments as you see fit and finalize the application for execution . . . ." (PX 77) Mr. Cohn classified Dr. Mower's invention as

> continually sens[ing] the activity of both the left and right ventricles, and when activity is sensed in either ventricle the device **immediately** electrically paces the other or both ventricles. Preferably, both ventricles are paced regardless of which ventricle fails to experience electrical activity, thereby ensuring that

> simultaneous contraction occurs, and also simplifying the required control and stimulating circuitry. However, for proper functioning of the device, only the non-active ventricle need be stimulated.

(PX 77) (emphasis in original) With respect to Mr. Nikolai's "window of coincidence," or delay between sensing and pacing, Mr. Cohn stated that to have a delay between sensing and pacing would undermine the purpose of the invention, i.e., to cause a simultaneous contraction of the ventricles. (PX 77)

9. On August 31, 1988, Mr. Nikolai responded to Mr. Cohn's letter with a letter to Dr. Mower. (PX 78) Mr. Nikolai expressed his confusion as to how the invention can sense the depolarization of one ventricle and then decide whether to pace the other ventricle without a delay period. (Id.) It seemed to Mr. Nikolai that, without such a delay, "both ventricles would have to be unconditionally stimulated whenever depolarization is detected in either ventricle," but this is not the invention Mr. Nikolai thought was originally described to him. (PX 78)

10. Dr. Mower responded to Mr. Nikolai on September 9, 1988. Dr. Mower stated that, in fact, both ventricles should be "'unconditionally stimulated whenever depolarization is detected in either ventricle.'" (PX 80) This is demand pacemaking "in the sense that the stimulus will cause a depolarization if needed, but if not needed to effect a depolarization, it does not cause the depolarization because it is delivered into the intrinsic deflection." (PX 80)

11. On December 30, 1988, Mr. Nikolai sent a copy of the patent application to Dr. Mower and requested that Dr. Mower review it. If Dr. Mower did not have any comments or corrections, he was introduced to execute the enclosed Declaration and Assignment[4] and return it to Mr. Nikolai. (PX 82)

12. On January 11, 1989, Dr. Mower sent Mr. Nikolai suggested changes to the application section discussing the background of the invention. (PX 84) His changes were incorporated into the application. (Compare PX 84, with PX 3)

13. Mr. Nikolai sent the patent application to the Patent and Trademark Office ("PTO") on January 19, 1989. (PX 156) On this same day, he sent a copy of the application to Stuart Rickerson at CPI. (PX 35)

14. On January 23, 1989, the patent application was formally filed with the PTO and assigned patent application number 07/299895 ("the '895 application").[5] (PX 3.02)

15. On June 9, 1989, the PTO examiner issued his first action, rejecting claims 1-14 and 17-22 of the '895 application. (PX 3.04) The examiner allowed claims 15 and 16. (Id.) Claims

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[4]Also on December 30, 1988, Mr. Nikolai sent a copy of the Assignment to Stuart Rickerson at CPI because Mr. Nikolai was not privy to CPI's assignment agreements and he wanted to make sure it was appropriately drafted. (PX 155)

[5]Mr. Nikolai sent notice of the formal filing and application number to Mr. Rickerson. (DTX 31)

2, 3, 8 and 9 were rejected as being obviousness in view of Nappholz[6] and Cohen.[7] (Id.) According to the examiner, Cohen showed "a means to sense a cardiac signal from the left or right ventricles [and it would be] obvious to use Cohen with the pacemaker in Nappholz . . . to more efficiently and effectively pace and sense the heart." (Id. at 3) The examiner explicitly noted that "the prior art does not show means to sense and stimulate both ventricles in a selective or alternate manner." (Id.)

16. In response to the examiner's rejections of claims 1, 4-7 and 12-14, Mr. Nikolai argued:

> [I]t is clear that the method being claimed involves detecting the respective cardiac signals originating in the left **and** the right ventricles of the heart. After analyzing those cardiac signals (or the absence thereof) in an electronic control circuit, electrical pulses are provided from a stimulating circuit to one, the other or both ventricles for effecting substantially simultaneous contraction of both ventricles. Clearly, Nappholz does not teach this method. The Nappholz patent describes a . . . pacemaker having a single atrial electrode and a single ventricular electrode . . . . Thus, the device of that patent is incapable of picking up ventricular depolarization signals from both ventricles.

(PX 3.05 at MED 267) (emphasis in original) With respect to claims 7, 12-14, Mr. Nikolai argued that they were distinguishable over Nappholz because they called for "sensing

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[6]U.S. Patent No. 4,378,020. (PX 3.04)

[7]U.S. Patent No. 4,774,950. (PX 3.04)

cardiac signals originating in the atrium, in both ventricles and then stimulating both ventricles in a fashion such that simultaneous contraction of the ventricles occurs after a predetermined A-V delay period." (Id.) According to this argument, Nappholz cannot simultaneously sense or pace in both ventricles. (Id.) With respect to claims 2, 3, 8 and 9, Mr. Nikolai asserted that they were not obvious in light of Nappholz and Cohen. (Id. at MED 268) Nappholz disclosed a pacemaker that sensed and selectively paced an atria and sensed and selectively paced a ventricle. (Id.) The Cohen prior art reference, Mr. Nikolai argued, had electrodes in the ventricles that paced but did not sense. (Id.) Thus, according to Mr. Nikolai, the two references did not suggest

> the idea of placing sensing electrodes in both the left and right ventricles and providing a control circuit capable of detecting the depolarization signals from both the left and right ventricles and to then provide control signals to a stimulating circuit that is used to stimulate one, the other or both ventricles whereby substantially simultaneous contraction of both ventricles . . . results.[8]

(Id.)

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[8]A copy of the arguments and amendments made in response to the first rejection was sent to Edward Gray, in house counsel for CPI. (PX 37; D.I. 123 at 359) As in-house counsel, Mr. Gray usually received communications from the attorneys prosecuting patents for CPI. (Id. at 230) He was not in the practice of forwarding these communications to inventors. (Id. at 230-31) Mr. Nikolai normally sent copies of amendments to CPI, and not to the inventors. (D.I. 123 at 365-66)

17. In response to these arguments, the examiner allowed claims 4 and 15-22, but rejected claims 7-9, 13 and 14 as being anticipated by Rockland[9] which, it was asserted, disclosed the structure of these claims. (PX 3.06) Claims 1, 2, 3 and 5 were rejected over Rockland because it would be "within the scope of the skilled artisan when utilizing the Rockland . . . invention." (Id. at 3) Claims 10, 23 and 25-27 were rejected as being obvious in light of Rockland and Funke,[10] as it would be "an obvious engineering design choice . . . to connect the ventricular electrodes in series, as shown by Funke." (Id.) Claims 11 and 24 were rejected because "[i]t would have been obvious to one of ordinary skill in the art to use McCorkle[11] with Rockland . . . and Funke in order to more efficiently and accurately pace/sense ventricular depolarizations." (Id.)

18. Mr. Nikolai cancelled claims 4, 17-14 and 25-27 and included the limitations of claim 4 into an amended claim 1, so that it stated:

> [S]aid step of analyzing including providing a control signal from said control circuit to said stimulating circuit for producing an electrical stimulating pulse to one or both ventricles in response to the absence of a detected cardiac signal from one or both ventricles

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[9]U.S. Patent No. 4,088,140. (PX 3)

[10]U.S. Patent No. 3,937,226. (PX 3)

[11]It is unclear which McCorkle reference the examiner is citing to, U.S. Patent No. 4,332,259 or 4,458,677.

within a time interval which is a small fraction of the pulse width of a detected cardiac signal.

(PX 3.07 at 1-2) This left claims 23 and 24 at issue. Mr. Nikolai amended claim 23 to include the following limitation:

> [F]or producing an electrical stimulating pulse to the left ventricle in the absence of a detected cardiac signal from the left ventricle, or to the right ventricle in the absence of a detected cardiac signal from the right ventricle, or to both ventricles in the absence of detected cardiac signals from both ventricles to effect substantially simultaneous contraction of both ventricles after a predetermined A-V delay period.

(Id. at 2) Mr. Nikolai remarked that the newly added limitation rendered claim 23 no longer obvious in light of Rockland and Funke, as Rockland failed to disclose a device to analyze signals from the right and left ventricles or to selectively pace the ventricle that is missing a normal cardiac signal. (Id. at 3-4) Furthermore, "[i]n applicant's arrangement, the stimulating pulses are applied to the plural sites only when none of these plural sites is producing a normal depolarization signal." (Id. at 4) Because claim 24 depended from claim 23, Mr. Nikolai argued that it too should be considered nonobvious.[12] (Id.)

19. The examiner and Mr. Nikolai conducted a telephone interview on December 5, 1989. (PX 3) The interview resulted in

[12]A copy of this response was sent to Mr. Gray at CPI. (PX 40; D.I. 123 at 360)

a formal examiner's amendment[13] making "minor wording changes to claims 15, 16, 19, 21 and 23." (Id.) Such wording changes were considered by the examiner to be a condition of allowance. (Id.) Most of the "minor wording changes" were directed towards claim 15. (PX 3.08) After the amendment, claim 15 (which is representative of the changes to claim 16) read:[14]

> A method for effecting simultaneous contraction of both left and right ventricles of a heart for improving hemodynamic efficiency comprising the steps of:
> separately sensing **for the presence of** cardiac **depolarization** signals from both left and right ventricles;
> **determining whether said cardiac depolarization signals are simultaneously present in both the left and right ventricles; and**
> stimulating at least one ventricle substantially simultaneously with the contraction of at least one other ventricle **in the event that said cardiac depolarization signals are determined not to be simultaneously present in both ventricles.**

(PX 3.08 at 2) (emphasis added)

20. The Notice of Allowability issued on December 11, 1989.[15] (PX 3.08) On April 23, 1990, Mr. Nikolai mailed this notice, copies of the amendments made to the '895 application and a copy of the application as it was originally filed to Dr.

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[13]Formal examiner's amendments can be used to correct "all errors and omissions in the claims . . . ." United States Patent and Trademark Office, Manual fo Patent Examining Procedure § 1302.04 (8th ed. 2003)

[14] The language in bold was added by the examiner.

[15]On December 20, 1989, Mr. Nikolai notified Mr. Gray and Mr. Cohn about the allowance. (PX 42)

Mower.[16] (D.I. 123 at 295; PX 88-92) On May 29, 1990, the '688 patent, titled "Method And Apparatus For Treating Hemodynamic Disfunction," issued to Morton Mower. (PX 1)

D. Prosecution Of The RE'119 Patent

21. On May 29, 1992, Mr. Cohn filed an application for reissue of the '688 patent on behalf of Dr. Mower. (PX 4)

22. Dr. Mower's first reissue declaration stated that he had "claimed less than [he] had a right to claim in the patent," as the claims inadvertently did not include the unconditional embodiment. (PX 4.02 at 2) Although Dr. Mower acknowledged that such an embodiment may be implicitly covered by the claims, he noted that they were not explicitly included despite being disclosed in the specification. (Id.) Furthermore, Dr. Mower asserted that he was not aware of the error until early in 1992. (Id. at 3)

23. On April 8, 1993, the examiner rejected the reissue claims 15-24, pursuant to 35 U.S.C. § 112, because the specification did not support the new claims. (PX 4.03) Specifically, the examiner noted that column 7, lines 45-50, cited by Dr. Mower in his declaration, discussed pacing both ventricles immediately, but claims 15-24 included pacing one **or**

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[16]Dr. Mower took the examiner's amendments to be clarifying changes. (D.I. 123 at 297-98) Dr. Mower also thought that the Notice of Allowability meant that prosecution was closed, so he did not review the claims as amended by the examiner. (Id. at 299)

both ventricles immediately. (Id. at 2) (emphasis in original) Claims 1-24, the original claims of the '688 patent, were rejected as being based upon a defective reissue declaration. (Id.) Claims 20-24 were rejected as being directed towards an apparatus when the subject matter of reissue was a method. (Id. at 2-3) Claims 15-19 were rejected for not particularly pointing out the subject matter that is the invention. (Id. at 3)

24. In response to this rejection, claims 15, 16, 19 and 20[17] were amended to more explicitly claim the unconditional embodiment. (PX 4) Along with the amendments, it was argued that the specification did describe the invention, i.e., col. 4, ll. 13-17; col. 4, l. 51-col. 5, l. 15; col. 5, ll. 50-63; and col. 7, ll. 45-50. (Id.)

25. On June 22, 1993, Dr. Mower filed a supplemental reissue application declaration. (PX 4.04) Dr. Mower again asserted that he had claimed less than he was entitled to because the claims did not include the unconditional pacing. (Id. at ¶¶ 5, 6, 8)

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[17]Claim 20 was amended along the same lines as claims 15 and 16. As originally drafted, one of its limitations read, "sensing a depolarization signal from one of the ventricles . . . immediately applying the stimulating pulse to the other or both ventricles." As amended it read, "sensing a depolarization signal from one of the ventricles . . . and immediately and unconditionally applying the stimulating pulse to both ventricles." (PX 4)

26. The examiner allowed reissue claims 1-18 and 20-24, but rejected claim 19. (PX 4) The examiner asserted that claim 19 was obvious in light of Baker[18] and Rockland and, for the same reasons, obvious in light of Baker and Funke.

27. In response to the rejection of claim 19, Mr. Cohn sought to add two claims, which he believed distinguished Baker, Rockland and Funke. Mr. Cohn argued that, because neither Baker nor Rockland (which was an improvement over Funke) taught pacing in both ventricles followed by an A-V delay period, claim 19 was not obvious in light of the prior art. (PX 4)

28. Upon request by the PTO, Dr. Mower filed a third reissue application declaration, in which he reasserted his statements made in previous declarations. (PX 4.09)

29. On May 3, 1994, the PTO mailed the notice of allowance of the reissue patent to Mr. Cohn. (PX 4)

30. On July 26, 1994, the Group Director withdrew the allowance and reopened prosecution of the reissue application. (PX 4)

31. On September 6, 1994, all 26 claims were rejected because the reissue declaration was defective as "it fail[ed] to particularly specify the errors relied upon . . . ." (PX 4.13)

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[18]Baker is U.S. Patent No. 4,624,260 and, according to the examiner, teaches all of the method steps of claim 19, except for stimulating both ventricles to cause a coordinated contraction. According to Mr. Cohn, Baker only teaches atrial sensing and pacing in one ventricle. (PX 4)

The rejection directed Dr. Mower to "point out very specifically how and when the errors arose or occurred," including "when and under what circumstances errors arose" and "facts indicating the manner in which the errors arose." (Id. at 2-3)

32. In response to this rejection, Dr. Mower filed another supplemental declaration for reissue, in which he again asserted that he had claimed less than he was entitled to. (PX 4.14)

33. The reissue application claims were rejected by the examiner on April 19, 1995, for lack of specificity. (PX 4.17)

34. On October 19, 1995, Dr. Mower submitted another supplemental reissue declaration. (PX 4.18) This time he asserted that

> [t]he attorney principally responsible for preparing and filing the application for [the '688 patent] was Mr. Thomas J. Nikolai. At the time the application was prepared, I was an employee of [CPI] and my principal work for CPI had been in the area of cardiac defibrallators. . . . At that time also, Mr. Nikolai and his firm, Haugen and Nikolai, P.A., had previously prepared and prosecuted patent applications for CPI but those applications were principally in the area of cardiac pacemakers. Mr. Nikolai and I had not previously worked together on the preparation or prosecution of a patent application for one of my inventions. During the preparation of this application Mr. Nikolai had difficulty understanding how my invention operated and thus did not appreciate the breadth and scope of the invention. As an example, a draft of the application which Mr. Nikolai prepared contemplated that when a depolarization signal was detected in a first ventricle, there would be a slight delay to detect whether a depolarization signal was present in the second ventricle before the second ventricle was stimulated. To the contrary, an important part of at least one aspect of my invention was the immediate and unconditional stimulation of the

> second ventricle upon sensing a depolarization signal in the first ventricle. Thus, much of the effort in preparing this application was directed to ensuring that Mr. Nikolai understood the invention and that it was accurately described in the application. I believe that the failure to include in that application claims such as new claims 15-26 resulted from lack of adequate communication between Mr. Nikolai and myself.

(Id. at ¶ 8) Dr. Mower also stated:

> As best I recall, I was not kept advised of the progress of my application while it was being prosecuted. I did not receive copies of any Office Actions when they were issued and was not consulted as to what responses should be filed. I did not have occasion to review that application or the amendments to it during its prosecution. I may have received a copy of the application and the amendments to it after prosecution had been completed and prior to the time the patent issued, but I do not recall reviewing the claims in any detail or considering their scope at that time.

(Id. at ¶ 9)

35. On April 22, 1998, Mr. Gray inquired into the status of the reissue application, as no correspondence had been received from the PTO since December 19, 1995. (PX 4)

36. A second notice of allowance was mailed on December 11, 2002. (PX 4)

III. CONCLUSIONS OF LAW

1. Federal patent law provides that

> [w]henever any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, **or by reason of the patentee claiming more or less than he had a right to claim in the patent**, the Director shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent for the **invention disclosed in the**

> **original patent**, and in accordance with a new and amended application, for the unexpired part of the term of the original patent. **No new matter shall be introduced into the application for reissue.**

35 U.S.C. § 251 (emphasis added). Section 251 has two distinct requirements: (1) the patent is defective, partly inoperative or invalid because of defects or because the patentee claimed more or less than he was entitled to; (2) the defect was caused by error without deceptive intent. See In re Amos, 953 F.2d 613, 616 (Fed. Cir. 1991); In re Wilder, 736 F.2d 1516, 1518 (Fed. Cir. 1984). Although the statute is liberally construed to allow patentees to correct defects in their patents, it is restricted in that a reissue patent cannot claim subject matter that could not have been claimed in the original patent.[19] See In re Amos, 953 F.2d at 617; In re Wilder, 736 F.2d at 1519.

2. Like any other patent, a reissue patent is entitled to a presumption of validity. See Westvaco Corp. v. Int'l Paper Co., 991 F.2d 735, 745 (Fed. Cir. 1993). Medtronic must prove by clear and convincing evidence that the RE'119 patent is invalid. Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1139 (Fed. Cir. 1985).

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[19]This includes a requirement that, when a patentee is asserting broader claims in the reissue application than are in the original patent, the broader claims are supported by an adequate disclosure within the original specification. See In re Weiler, 790 F.2d 1576, 1580 (Fed. Cir. 1986). In this case, it is not alleged that the broader claims of the RE'119 patent are not supported by the specification or written description. Therefore, this requirement is not addressed here.

A. Error Justifying Reissue

3. Medtronic argues that there was no error during prosecution of the '688 patent to justify reissuing the patent under § 251. Defendants assert that, as stated in Dr. Mower's fifth declaration, the error was attorney error that resulted from Mr. Nikolai's failure to understand the technology of the invention.

4. "The statutory standard of reissuable error is objective and does not require proof of [the patentee's] subjective state of mind." Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1575 (Fed. Cir. 1991). Nevertheless, a showing that a patentee intended to claim matter that he, in fact, did not claim "can go a long way to support a finding that error occurred; and, conversely, a showing that an applicant never had any such intent makes a finding of error extremely difficult if not impossible." In re Weiler, 790 F.2d 1576, 1581-82 (Fed. Cir. 1986).

5. "An attorney's failure to appreciate the full scope of the invention is one of the most common sources of defects in patents" and such an error is sufficient to justify reissuing a patent. In re Wilder, 736 F.2d at 1519. It is not necessary that the error be unavoidable or that the error could not have been discovered by the patentee through proper communication with the prosecuting attorney. Id.

6. Dr. Mower's fifth reissue declaration, which was the basis of the reissue patent, states that the unconditional embodiment was improperly excluded from the claims of the '688 application due to attorney error and his attorney's failure to understand his invention. (PX 4.18) The specification of the '895 application and the '688 patent evidences that Dr. Mower intended to claim the unconditional embodiment. The specification explicitly states that the unconditional embodiment is comprehended to be an embodiment of the invention. ('688 patent, col. 4, ll. 4-6, col. 5, ll. 29-31, 35-43, col. 7, ll. 45-50) During the drafting of the '895 application, Dr. Mower paid particular attention to the specification in order to ensure that it included all aspects of his invention. (D.I. 123 at 286) Despite the references in the specification, including the unconditional embodiment in the invention, the embodiment was not included in the claims of the '688 patent. See infra Part III at ¶ 19.

7. Likewise, the communications between Dr. Mower and Mr. Nikolai prove that the unconditional embodiment was always understood by Dr. Mower to be part of the invention. While Mr. Nikolai was drafting the '895 application, Mr. Cohn, after speaking with Dr. Mower, characterized Dr. Mower's invention as including the unconditional embodiment. (PX 77) In response, Mr. Nikolai expressed some confusion as to whether the

unconditional embodiment would work. (PX 78) At this time, Dr. Mower expressed to Mr. Nikolai that the invention included the unconditional embodiment. (PX 80) Still, Mr. Nikolai testified that he had a difficult time comprehending the unconditional embodiment and there is evidence that he did not think it would work. (D.I. 123 at 371; PX 78) Based on this evidence, the court concludes that the unconditional embodiment was intended to be included in the claims and the embodiment was excluded from the claims due to attorney error.

B. Declaration of Reissue

8. Medtronic asserts that Dr. Mower's declarations of reissue, particularly his fifth reissue declaration, are inadequate and, therefore, the RE'119 patent is invalid.

9. When a patentee files a reissue application, he is required to file a declaration stating that:

> (1) [he] believes the original patent to be wholly or partly inoperative or invalid by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than the patentee had the right to claim in the patent, stating at least one error being relied upon as the basis for reissue; and
> (2) [a]ll errors being corrected in the reissue application up to the time of filing of the oath or declaration . . . arose without any deceptive intention on the part of the applicant.

37 C.F.R. § 1.175 (2005).[20] Under this regulation, the patentee is only required to disclose a single error to be corrected and a general statement that the error arose without deceptive intent. Shockley, 248 F.3d at 1358.

10. Dr. Mower's fifth reissue declaration complies with these requirements. Dr. Mower expressed his belief that he thought the '688 patent was inoperative because he claimed less than he had a right to. (PX 4.18 at ¶ 5) Dr. Mower's assertion of error was specific, as he stated that he failed to claim the unconditional embodiment and how the reissue claims rectified that error. (Id.)

11. Dr. Mower states that the failure to claim the unconditional embodiment was the result of attorney error. (Id. at ¶ 8) Attorney error is a recognized "error" under § 251 and, in fact, it is the most common error. See 37 C.F.R. § 1.175; In re Wilder, 736 F.2d at 1519. As stated earlier, the evidence at trial supported Dr. Mower's assertion of attorney error.

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[20]Section 1.175 was amended in 1997. Before this amendment, the section required the patentee to "declare in detail the nature and origin of each error." Shockley v. Arcan, Inc., 248 F.3d 1349, 1358 (Fed. Cir. 2001). The pre-amendment § 1.175 was applied by the PTO to reject Dr. Mower's first four reissue declarations. The amendment took effect December 1, 1997, and the Federal Circuit has held that amended § 1.175 applies to all reissue applications pending as of that date. Id. at 1358-59. The reissue application in this case was pending until 2002; therefore, the court applies § 1.175 as it was amended in 1997.

12. Medtronic contends that Dr. Mower misrepresented the attorney error to the PTO when he asserted that Mr. Nikolai was the principal patent attorney responsible for drafting and filing the '895 application. There is, however, sufficient evidence supporting Dr. Mower's statement. Mr. Nikolai was the patent attorney who filed the '895 application and communicated with the PTO. (PX 3) Dr. Mower executed a power of attorney to Mr. Nikolai, giving Mr. Nikolai the authority to file the patent on his behalf. (PX 3) Although Mr. Cohn played a role in drafting the '895 application and, in fact, drafted claims that were part of the '895 application, there is no evidence that anyone other than Mr. Nikolai was **principally responsible** for the '895 application. Mr. Cohn never made changes to the application once it was sent to Mr. Nikolai and the only changes he communicated to Mr. Nikolai were those suggested by Dr. Mower. (PX 76; PX 77; D.I. 123 at 276-80)

13. Medtronic also argues that Dr. Mower misrepresented the error when he asserted that he was not kept advised of the progress of his application. The evidence shows, however, that Dr. Mower was not kept apprised of the **prosecution** of the '688 patent. Mr. Nikolai only sent copies of the amendments to CPI and those copies were never given to Dr. Mower. (D.I. 123 at 230-31, 271, 362-64, 365-66, 370-71) Even when Dr. Mower requested information about the progress of the '895 application,

CPI did not relay the correspondence from Mr. Nikolai. (D.I. 123 at 271-72) Despite these communications with CPI, Mr. Nikolai admitted that he did not keep CPI, or Dr. Mower, apprised of the prosecution of the '895 application, but he did communicate with them with respect to drafting the '895 application. (D.I. 123 at 405)

14. Dr. Mower's fifth declaration stated that the error was without deceptive intent. He specifically details when and how he became aware of the error. He includes information with respect to communications with his attorney, or lack thereof, as part of the reason he failed to recognize the error sooner. (Id. at ¶¶ 9-12) This complies with the requirements of amended § 1.175.

15. Therefore, the court finds Dr. Mower's fifth declaration sufficient to support the RE'119 patent.

C. Recapture Rule

15. Medtronic argues that the RE'119 patent is invalid because it improperly recaptures subject matter that was surrendered during prosecution of the '688 patent. Specifically, Medtronic asserts that Dr. Mower surrendered the unconditional embodiment and any embodiment that does not separately sense depolarization signals in each ventricle. Defendants assert that the claims of the '895 application did not include the unconditional embodiment and, therefore, the unconditional

embodiment is not subject matter that was surrendered during prosecution. Likewise, according to defendants, Dr. Mower never surrendered a device that senses depolarizations in only one ventricle.

16. Reissue proceedings cannot be used to obtain subject matter that could not have been included in the original patent. See, e.g., In re Watkinson, 900 F.2d 230, 232 (Fed. Cir. 1990) (citations omitted). The recapture rule prevents such an occurrence by prohibiting a "patentee from acquiring, through reissue, claims that are of the same or broader scope than those claims" that were amended during the original prosecution. See Ball Corp. v. United States, 729 F.2d 1429, 1436 (Fed. Cir. 1984). The recapture rule, however, does not apply in the absence of evidence that an amendment or cancellation was "'an admission that the scope of that claim was not in fact patentable.'" In re Clement, 131 F.3d 1464, 1469 (Fed. Cir. 1997). Often a patentee's intent in amending claims, or in acquiescing in the amendment of the claims, is not evident. The Federal Circuit has stated, however, that "[d]eliberately . . . amending a claim in an effort to overcome a reference strongly suggests that the applicant admits that the scope of the claim before the . . . amendment is unpatentable, but it is not dispositive because other evidence in the prosecution history may indicate to the contrary." In re Clement, 131 F.3d at 1469.

17. When the recapture rule applies, it requires a three step process. First, the court must "'determine whether and in what 'aspect' the reissue claims are broader than the patent claims.'"[21] Pannu v. Storz Inst., Inc., 258 F.3d 1366, 1371 (Fed. Cir. 2001) (quoting Clement, 131 F.3d at 1468). Second, the court must "'determine whether the broader aspects of the reissued claim related to surrendered subject matter.'" Id. "[I]f the reissue claim is as broad as or broader than the . . . amended claim in all aspects, the recapture rule bars the claim . . . ." In re Clement, 131 F.3d 1464, 1470 (Fed. Cir. 1997). If the claims are narrower in all aspects than the amended claims, then "the recapture rule does not apply." Id. Third, "the court must determine whether the reissued claims were materially narrowed in other respects to avoid the recapture." Pannu, 258 F.3d at 1371. Claims that are broader and not narrowed in a way that is germane to the prior art rejection at issue are barred by the recapture rule. Id.

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[21]With respect to the unconditional embodiment, this first step has been satisfied. Defendants concede that the claims of the '688 patent did not include the unconditional embodiment and that the claims of the RE'119 patent include both the conditional and unconditional embodiment; thus, the RE'119 patent is necessarily broader in scope than the '688 patent.

1. The Unconditional Embodiment

a. Surrender By Amendment

18. The claims of the '895 application that include the unconditional embodiment are claim 15, which became claim 5 of the '688 patent, and claim 16, which became claim 6 of the '688 patent.[22] Claim 15 discloses:

> A method for effecting simultaneous contraction of both left and right ventricles of a heart for improving hemodynamic efficiency comprising the steps of:
> separately sensing cardiac signals from both left and right ventricles; and
> **stimulating at least one ventricle** substantially simultaneously **with the contraction of at least one other ventricle**.

(PX 3.02) Claim 16 provides:

> A method of effecting simultaneous contraction of both left and right ventricles of a heart for improving hemodynamic efficiency comprising the steps of:
> sensing the cardiac signals of the atria and separately sensing the cardiac signals of both the left and right ventricles; and
> **stimulating at least one ventricle simultaneously with the contraction of at least one other ventricle** after a predetermined A-V period.

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[22]Medtronic failed to carry its burden of showing that claims 1, 7 and 23 include the unconditional embodiment. Claim 1 requires that the device "analyz[e] said cardiac signals and the absence thereof." (PX 3.02; 3.05) Claim 7 is limited to a device with a "control circuit connected to said sensing means to analyze the cardiac signals and provide a control signal." (PX 3.02) Claim 23 also includes the means for analyzing depolarization signals and refers to the "ECG amplifier means," which is defined in the specification as "processing sensed cardiac signals." (PX 3.05) In the unconditional embodiment, the device does not analyze or process any signals, as it immediately and unconditionally stimulates the ventricles.

(Id.) Both claims describe a device that paces **at least one** ventricle after the contraction of **at least one** ventricle or atria and, as such, the claims necessarily include unconditional pacing, i.e., immediately pacing both ventricles. Such an interpretation of these claims is supported by the references to unconditional pacing in the specification of the '895 application. (PX 3.02 at 9, ll. 18-22, 25-27; Id. at 14, ll. 4-7)

19. Claims 15 and 16 were not amended until, at the end of prosecution, the examiner made "minor wording changes" to them. (PX 3.08) The examiner's amendment added a limitation to both claims that required a determination of whether there were depolarization signals in both the left and right ventricles and, if such signals were not simultaneously present, stimulation of at least one ventricle. Thus, the examiner narrowed the claims to exclude immediate and unconditional pacing.

20. Neither claim 15 nor 16 was ever rejected by the examiner as anticipated or obvious over the prior art. Only the claims of the '895 application that described the conditional embodiment were subject to such rejections. The additions of the limitations to claims 15 and 16 were characterized by the examiner as minor wording changes, thus indicating that he thought he was clarifying the invention, not surrendering an embodiment. Because there is no clear admission that the

unconditional embodiment was not patentable, the court concludes that the recapture rule does not apply to the reissue claims that include the unconditional embodiment.

b. Surrender By Argument

21. An amendment to a claim is not the only way a patentee can surrender subject matter during prosecution. Hester Indus., Inc. v. Stein, Inc., 142 F.3d 1472, 1482 (Fed. Cir. 1998). Arguments made during prosecution can serve to surrender subject matter and, when such surrendered subject matter appears in the reissue claims, the recapture rule applies. Id. Medtronic argues that Dr. Mower surrendered the unconditional embodiment with the arguments he made to distinguish the prior art during prosecution.

22. In response to the first rejection, Mr. Nikolai distinguished the Nappholz reference by arguing that the method of the invention was separately sensing depolarizations, analyzing those depolarizations and then pacing one, the other or both ventricles. (PX 3.05) He went on to assert that Nappholz did not teach such an invention because it only had a single ventricular electrode and was incapable of sensing and pacing both ventricles. (Id.) Such an argument does not surrender the unconditional embodiment because it is directed towards the fact that Nappholz only discloses one electrode, not whether Nappholz immediately and unconditionally paces both ventricles.

Similarly, Mr. Nikolai distinguished the Cohen reference because it did not have electrodes that could both sense and pace, and not because of the way it paced the ventricles.

23. In response to the second rejection, Mr. Nikolai addressed the Rockland prior art. He argued that Rockland did not render the claims of the '895 application obvious because the invention of Rockland was not described as a device that could selectively analyze the ventricular depolarizations but, rather, Rockland described a device that paced a plurality of sites over a predetermined time period. These arguments do not necessarily render the unconditional embodiment unpatentable because the unconditional embodiment immediately paces the ventricles and, therefore, has no predetermined time period. In addition, the examiner never rejected unamended claims 15 or 16 of the '895 application as anticipated or obvious over the prior art, even though both claims included the unconditional embodiment. Therefore, Medtronic has not carried its burden of proving, by clear and convincing evidence, that these arguments relate to and render the unconditional embodiment unpatentable.

2. An Embodiment Without Separately Sensing Electrodes

24. The claims of the '895 application did not include an embodiment with only one sensing electrode. All of the claims of the '895 application refer to some means of sensing in **both** the right **and** left ventricles. (PX 3.02 at 15-20) Contrary to

Medtronic's argument that claim 7 of the '895 application describes a device that senses in only one ventricle, claim 7 specifically refers to "bi-ventricular pacing" with "a control circuit connected to said sensing means to analyze the cardiac signals." (PX 3.02 at 16) Such a pacemaker would require sensing in both ventricles in order to analyze those signals. See supra note 24; supra Part II.B. at ¶ 5. Also, the specification uses "bi-ventricular pacing" in reference to sensing in both the left **and** the right ventricles. (PX 3.02 at 11) Therefore, the court finds that claim 7 discloses devices that sense in both ventricles.

25. Likewise, the claims of the '688 patent disclose a device with two sensing electrodes because each claim refers to some form of "detecting respective cardiac signals originating in the left **and** right ventricles of the heart . . . ." ('688 patent, col. 8, ll. 3-4 (emphasis added); see also '688 patent, col. 8, ll. 42-44, 55-58, col. 9, ll. 1-7, 21-23, col. 10, ll. 22-25)

26. Claim 15 of the RE'119 patent, however, claims a device with only one ventricular sensing electrode (as it requires only "detecting a cardiac depolarization signal originating from a first ventricle") and two pacing electrodes (as it paces both ventricles unconditionally). (RE'119 patent, col. 10, ll. 3-4)

27. Because the RE'119 patent is broad enough to include a device with one sensing electrode, and the claims of the '688 patent require two sensing electrodes, the RE'119 patent is necessarily broader in scope than the '688 patent. See Hester, 142 F.3d at 1480 ("A reissue claim that does not include a limitation present in the original patent claims is broader in that respect.").

28. The question becomes whether the broadened subject matter relates to any amendments or subject matter surrendered during prosecution. As previously stated, arguments made during prosecution can serve to surrender subject matter and, when such surrendered subject matter appears in the reissue claims, the recapture rule applies. See Hester, 142 F.3d at 1482. However, a patentee cannot surrender through amendment what he never claimed to begin with. Because the claims of the '895 application did not include an embodiment without two sensing electrodes, the patentee did not surrender subject matter via an amendment during prosecution.

29. During prosecution of the '688 patent, the Nappholz reference was distinguished because it did not have two sensing electrodes and it also did not have two pacing electrodes. According to Mr. Nikolai, this meant that the Nappholz device was "incapable of picking up ventricular depolarization signals from both ventricles and for ultimately providing stimulation to both

ventricles," which was characteristic of the invention of the '688 patent. (PX 3.05) Assuming that these statements are sufficient to surrender subject matter during prosecution, the surrendered subject matter, i.e., a pacemaker with **one** ventricular pacing electrode, does not appear in the reissue claims. The device of claim 15 of the RE'119 patent explicitly requires pacing in both ventricles. (RE'119 patent, col. 10, ll. 5-8) This means that claim 15 requires a pacing electrode in each ventricle. This does not recapture the subject matter allegedly relinquished to distinguish Nappholz, as the Nappholz device only allowed for one pacing electrode. Therefore, claim 15 is materially narrowed and would have been patentable over Nappholz. Dr. Mower is not recapturing subject matter that was not patentable at the time the '688 application issued.

30. Likewise, assuming the arguments made to distinguish Cohen surrendered subject matter, Medtronic did not carry its burden of showing that such subject matter appears in the reissue claims. The Cohen prior art was distinguished because it only had electrodes that paced and did not sense depolarizations. (PX 3.05) Such an embodiment is not included in the reissue claims, which require at least one electrode that can both sense and pace.

31. During prosecution of the '895 application, the Rockland prior art was distinguished because it did not have

analyzing circuitry and it paced the heart over a predetermined time period at a plurality of points upon sensing depolarizations. The reissue claims require immediate and unconditional pacing of only the ventricles upon depolarization. These claims do not include the embodiment disclosed in Rockland because they do not include a predetermined time period or pacing at more than two points. Medtronic has not shown, by clear and convincing evidence, that the broader reissue claims include subject matter that was unpatentable over Rockland.

32. Therefore, the court concludes that, while the claims of the RE'119 patent are broader than those in the '688 patent, they are materially narrowed so as to not recapture the subject matter given up during prosecution. The recapture rule does not apply.

IV. CONCLUSION

For the reasons stated, the RE'119 patent is not invalid as inappropriately reissued or as recapturing subject matter that was originally unpatentable. An appropriate order shall issue and judgment shall be entered accordingly.